

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

IN RE: AREDIA AND ZOMETA)
PRODUCTS LIABILITY LITIGATION)
) NO. 3:06-MD-1760
This Document Relates to Case Numbers:) JUDGE CAMPBELL
3:07-1194, 3:06-0368 and 3:06-0393)

MEMORANDUM

Pending before the Court is Defendant's Motion for Summary Judgment on the Claims of Plaintiffs Fragomeli, Biocca and Cuthbert (Docket No. 857). For the reasons stated herein, Defendant's Motion is GRANTED, and the claims of Plaintiffs Fragomeli, Biocca and Cuthbert are DISMISSED with prejudice.

Defendant's Motion for Summary Judgment asks the Court to dismiss the claims of three Plaintiffs in this multidistrict products liability litigation. It is undisputed that claims of the three Plaintiffs at issue are governed by Michigan substantive law. Defendant claims that Michigan law, specifically Mich. Comp. Laws § 600.2946(5), and federal preemption law preclude the products liability claims of these three Plaintiffs.

SUMMARY JUDGMENT

Summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); Meyers v. Columbia/HCA Healthcare Corp., 341 F.3d 461, 466 (6th Cir. 2003). In deciding a motion for summary judgment, the court must view the factual evidence

and draw all reasonable inferences in favor of the nonmoving party. Id.; Hopson v. DaimlerChrysler Corp., 306 F.3d 427, 432 (6th Cir. 2002).

To prevail, the non-movant must produce specific evidence that demonstrates there is a genuine issue of material fact for trial. Meyers, 341 F.3d at 466. A mere scintilla of evidence is insufficient; there must be evidence on which the jury could reasonably find for the non-movant. Id. The non-moving party may not rest on mere allegations but must set forth specific facts showing that there is a genuine issue for trial. Hopson, 306 F.3d at 432.

DISCUSSION

The State of Michigan has adopted a products liability statute that immunizes drug manufacturers from liability from damages in suits contending that their drug was defective or unreasonably dangerous, subject to certain exceptions. Garcia v. Wyeth-Ayerst Laboratories, 385 F.3d 961, 963-64 (6th Cir. 2004). The Michigan statute provides:

In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.

Mich. Comp. Laws, § 600.2946(5).

The statute does not apply if the defendant, at any time before the event that allegedly caused the injury, (1) intentionally withheld from or misrepresented to the FDA information concerning the drug that is required to be submitted under federal law, and the drug would not have been approved or the FDA would have withdrawn approval if that information had been accurately submitted, or (2) made an illegal payment to an official or employee of the FDA for the purpose of securing or maintaining approval of the drug. Mich. Comp. Laws, § 600.2946(5)(a) and (b).

The drugs at issue in this case, Aredia and Zometa, were approved by the FDA.¹ Therefore, unless Plaintiffs can show that Defendant falls within an exception, the Michigan statute is an absolute defense to Plaintiffs' claims.

The U.S. Supreme Court has held that state law fraud-on-the-FDA claims are preempted by federal law. White v. Smithkline Beecham Corp., ___ F.Supp. 2d ___, 2008 WL 612354 at * 3 (W.D. Mich. March 6, 2008) (citing Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001)). Thus, any attempt to prove the fraud on the FDA as set forth in these exceptions is foreclosed by federal preemption law. Garcia, 385 F.3d at 966. The fraud-on-the-FDA exception is preempted by federal law unless the FDA itself determines that it was defrauded. Duronio v. Merck & Co., Inc., 2006 WL 1628516 at * 5 (Mich. App. June 13, 2006).

Because these issues are preempted by federal law, the circumstances surrounding the FDA's approval of a drug cannot be litigated in the course of this private products liability suit brought under Michigan law. See Zammit v. Shire Us, Inc., 415 F.Supp.2d 760, 767 (E.D. Mich. 2006). Although other federal courts have disagreed with Garcia,² this Court is bound by the Sixth Circuit precedent.

¹ Plaintiffs' responses to Defendant's Statement of Undisputed Facts on this issue do not create a genuine issue of material fact for purposes of summary judgment. Docket No. 1079, ¶¶ 16-21.

² See, e.g., Desiano v. Warner-Lambert & Co., 467 F.3d 85 (2d Cir. 2006), which was affirmed by an equally divided Court in Warner-Lambert Co. v. Kent, 128 S.Ct. 1168 (2008). Affirmance by an equally divided Court is entitled to no precedential weight. Neil v. Biggers, 409 U.S. 188, 192 (1972).

Accordingly, Defendant's Motion for Summary Judgment is GRANTED. The claims of these three Plaintiffs are precluded by Michigan law; and Plaintiffs are precluded, by federal preemption law, from attempting to prove that either exception applies.

Plaintiffs ask for additional time for discovery, but additional discovery on this issue would be futile. As explained above, Plaintiffs cannot present evidence in this case, even if it is discovered, that Defendant defrauded the FDA. Plaintiffs also ask that they be allowed, if the Court finds for Defendant on this Motion, to dismiss their claims without prejudice. The Court denies Plaintiffs' request. The Defendant is entitled to summary judgment on this issue based on the controlling law in the Sixth Circuit.

For all these reasons, Defendant's Motion for Summary Judgment (Docket No.857) is GRANTED, and the claims of Plaintiffs Fragomeli, Biocca and Cuthbert are DISMISSED.

IT IS SO ORDERED.



TODD J. CAMPBELL
UNITED STATES DISTRICT JUDGE